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By: 

PATENT
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

MARC ODRICH *et al.*

Application No.: 10/600,027

Filed: June 19, 2003

For: METHOD AND SYSTEMS FOR
LASER TREATMENT OF
PRESBYOPIA USING OFFSET
IMAGING

Confirmation No. 5696

Examiner: David M. Shay

Technology Center/Art Unit: 3735

REPLY BRIEF

Mail Stop Appeal Brief
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Appellant offers this Reply Brief in furtherance of the Examiner's Answer mailed
February 26, 2007.

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1. STATUS OF CLAIMS

Claims 1-15 are currently pending and are the subject of this appeal. No other claims are pending. Claims 1-9 have been rejected under 35 U.S.C., §112, first paragraph. Claims 10-15 have been rejected under 35 U.S.C. §103(a) over Frey (U.S. Patent No. 6,027,494) in view of Largent (U.S. Patent No. 6,312,424). Claims 10-15 have been rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-15 of U.S. Patent No. 6,280,435. Claims 1-15 have been rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-35 of U.S. Patent No. 6,663,619. All pending claims are being appealed in the subject application.

Claims 11-15 were previously rejected under 35 U.S.C. §112, second paragraph, in the Office Action mailed July 25, 2005. However, these rejections were overcome by Appellant's response mailed October 24, 2005.

The Examiner's Answer was mailed on February 26, 2007. Pursuant to the Answer, the Examiner has withdrawn the following rejections, which were previously pending:

- The rejection of claims 10-15 under the judicially created doctrine of obviousness-type double patenting over claims 1-15 of U.S. Patent No. 6,280,435; and
- The rejection of claims 1-15 under the judicially created doctrine of obviousness-type double patenting over claims 1-35 of U.S. Patent No. 6,663,619.

All other previously pending rejections were maintained pursuant to the Examiner's Answer. As such, the current status of the claims is as follows:

Claims 1-9 stand rejected under 35 U.S.C., §112, first paragraph.

Claims 10-15 stand rejected under 35 U.S.C. §103(a) over Frey (U.S. Patent No. 6,027,494) in view of Largent (U.S. Patent No. 6,312,424).

2. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 1-9 are properly rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

Whether claims 10-15 are properly rejected under 35 U.S.C. § 103(a) as being unpatentable over Frey (U.S. Patent No. 6,027,494) in combination with Largent (U.S. Patent No. 6,312,424).

3. ARGUMENT

A. Whether claims 1-9 are properly rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

Claims 1-9 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

Appellants respectfully traverse this rejection for at least the reasons previously made of record and additionally submit the following remarks in reply to additional comments made in the Examiner's Answer, mailed February 26, 2007. In particular, Appellants maintain that the subject matter of claims 1-9 was sufficiently described in the originally filed application so as to satisfy the "written description" requirement of 35 U.S.C. § 112, first paragraph, because 1) claims 1-9 as originally filed are considered part of the specification and adequately supported; and 2) the subject matter of original claims 1-9 is additionally well supported throughout the specification and figures of the application as filed. Having provided support throughout the specification for originally filed claims 1-9, and absent any evidence to the contrary, adequate "written description" has been provided. In this case, the Examiner has simply failed to present any evidence or rationale that would suggest a lack of adequate written description support for the originally filed claims 1-9.

In the Examiner's Answer, the Examiner incorrectly characterizes Appellants' written description support as being limited solely to "the mere inclusion of claims in the originally filed application" (Examiner's Answer, Item #10A). While originally filed claims do constitute their own written description support, the Examiner has ignored the support that is found throughout the specification as filed and which has previously been identified by

Appellants (e.g., Appellants' Brief, mailed 9/25/2006, page 6). For example, adjusting an ablation cut profile of the multifocal ablation shape in response to the size of the pupil is well described throughout the specification, e.g., at paragraphs 0025-0027, 0059-0060, 0070-0071, and Figures 1, 2, 3, and 8 of the originally filed application. In addition to describing the subject matter of claims 1-9 in detail, the specification discloses that the methods described therein have actually been implemented with effective results. See, e.g., page 17, lines 13-15; page 18, lines 13-14. As such, one skilled in the art would recognize that the Appellant was in possession of the originally claimed invention at the time of filing.

The Examiner additionally incorrectly argues that the "Appellant also makes reference to 'the strong presumption of adequate written description', however provides no authority upon which to base this statement". (Examiner's Answer, Item #10A). However, Appellants have provided multiple citations to authority supporting the identified presumption that an adequate written description of the originally claimed invention is present when the application is filed (e.g., Appellant's Brief, paragraph bridging pages 6 and 7). For the Examiner's convenience, and in order to further provide the desired support, attention is respectfully drawn to MPEP §2163(I)(A), the very first sentence of which states the following:

There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed. *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976)
[Emphasis Added]

Moreover, MPEP §2163.04, which is entitled "Burden on the Examiner with Regard to the Written Description Requirement" provides that "[t]he examiner has the initial burden of presenting by preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims" (emphasis added). In the present case, the Examiner has failed to meet this burden.

The Examiner additionally argues that evidence of the alleged lack of written description support has been provided in the form of "the article to Sher *et al*", which allegedly has not been rebutted by Appellants. As previously made of record, however, in focusing on

paragraph 0022 of the current specification (i.e., argument for which Sher et al. is cited in support), the Examiner is inappropriately ignoring the language of the pending claims currently under examination.

In order to be fully responsive, however, and to more specifically address the cited reference, Appellants further submit that the relevancy of the cited reference is ambiguous at best, and certainly fails to provide the requisite preponderance of evidence demonstrating the alleged lack of possession at the time of the invention. First, the Examiner has not established that Sher et al. is representative of the state of the art at the time of the invention, since the article to Sher et al. predates the filing date of the present application by some 8 years. Second, rather than being directed to mitigation of presbyopia, as recited in claims 1-9 of the current case, Sher et al. focuses on correction of high myopia in a small cross-section of the population in which photorefractive keratectomy (PRK) was found particularly challenging (see, e.g., page 77, first paragraph). Third, regardless of any particular challenges of PRK in the specific sub-population of patients of Sher et al., the cited reference actually teaches successfully treating high myopia in a large portion of these patients (see, e.g., Sher et al., page 78, Figure 6-1). Thus, despite any "variations" in surgical outcomes noted by the Examiner, Sher et al. actually teaches effectively treating a large portion of the target population. Thus, if anything, the successful treatment of high myopia patients as described in Sher et al. might actually further indicate Appellants' possession of the claimed invention at the time of the invention.

In the instant case, the Examiner has done little other than state that variability exists in cornea healing, followed by a conclusory rejection of the claims. The Examiner has failed to fully articulate the relevancy of the cited specification provision (paragraph 0022) to the pending claims, or offer any explanation as to why the skilled artisan would disregard the effective results reported both in the cited reference (Sher et al.) for high myopia, or those reported in the present specification for mitigating presbyopia.

In the instant case, the current claims are supported by the originally filed claims and described throughout the specification, including disclosure that the methods described therein have actually been implemented clinically with effective results. Thus, for at least the above reasons and those previously made of record, Appellants maintain that, in this case, the

Examiner has failed to meet the requisite burden of the PTO and demonstrate by a preponderance of the evidence that a person skilled in the art would not recognize Appellant to be in possession of the claimed invention at the time of filing. Accordingly, the rejections of claims 1-9 under the first paragraph of 35 U.S.C. § 112 are improper and should be withdrawn.

B. Whether claims 10-15 are properly rejected under 35 U.S.C. § 103(a) as being unpatentable over Frey (U.S. Patent No. 6,027,494) in combination with Largent (U.S. Patent No. 6,312,424).

Claims 10-15 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Frey in view of Largent.

Appellants respectfully traverse this rejection for at least the reasons previously made of record and additionally submit the following remarks in reply to additional comments made in the Examiner's Answer, mailed February 26, 2007. In particular, Appellants maintain that the Examiner has failed to establish at least two of the requirements for a case of *prima facie* obviousness: 1) there is no suggestion or motivation to combine the cited references; and 2) even if combined, the cited references, alone or in combination, would fail to teach or suggest each and every element of the current claims. The arguments in the Examiner's Answer fail to rebut Appellants previous remarks regarding lack of *prima facie* obviousness.

Regarding any reason for combining the cited references in the first place, Appellants previously pointed out, *inter alia*, that the specific disregard of pupil size in the teachings of Largent would actually weigh against the proposed modification of Largent with the teachings of Frey to include adjusting ablation shape based on pupil size. The Examiner has disputed Appellants' use of the term "one size fits all" with respect to the outer ablation shape taught by Largent, but admits that Largent is silent as to adjusting the outermost ablation diameter or shape, and completely disregards pupil size, in determining cornea ablation shape. Thus, Appellants underlying contention (e.g., Largent's disregard of the outer periphery of the ablation shape and of pupil size would weigh against the proposed combination of references) has not been rebutted by the Examiner.

A case of obviousness requires ascertaining the scope and contents of the cited references, and ascertaining the differences between the cited references and the claims at issue, as well as the level of ordinary skill in the art. *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966). In the present case, against this background, Appellants respectfully maintain that a case of obviousness in view of the cited references would not be found because not only would the proposed combination fail to teach the claimed invention, but the specific disregard of pupil size in the teachings of Largent would actually weigh against the proposed combination - i.e., modifying Largent with the teachings of Frey to include adjusting ablation shape based on pupil size.

In regard to the comments of the Examiner's Answer, Section 10(B), last full paragraph, Appellants respectfully disagree with the Examiner's characterization of Appellants' remarks from the Appeal Brief. Attention is respectfully drawn to the Appeal Brief, pages 12-13, and more generally to pages 8-15, for an accurate representation of Appellants' positions.

Furthermore, Appellants respectfully submit that the cited provision of Largent (Largent col. 1, lines 57-59) adds nothing to the rejection and the references would still fail to render the current claims *prima facie* obvious (see, e.g., Examiner's Answer, Section 10(B), last full paragraph). While Largent teaches vision correction via shaping multiple regions of a cornea to correct vision at multiple corresponding distances (e.g., Largent col. 1, lines 57-59), Largent does not teach adjusting any aspect of an ablation shape based on pupil size. Frey teaches adjustment of only the outer periphery of an ablation shape. Thus, even if one of ordinary skill were to combine the teachings of Frey with those of Largent (even though there would be no suggestion/motivation to do so), the proposed combination would still at least fail to teach "determining the distribution of laser beam pulses to ablate the first and second regions of the multifocal ablation shape, where the distribution is determined in response to a signal related to size of the pupil...", as recited in claim 10.

Thus, for the above reasons, as well as reasons previously made of record, the Office has failed to establish a *prima facie* case of obviousness with respect to the claimed invention. Accordingly, Appellants respectfully request that the rejection of claims 10-15 under 35 U.S.C. § 103 be withdrawn and the claims be allowed.

4. CONCLUSION

For these reasons, it is respectfully submitted that the rejection should be reversed.

Respectfully submitted,

Dated: _____

4/20/2007

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